

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Improved Live-Attenuated Vaccine for Respiratory Syncytial Virus

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Summary Information section of this notice to Codagenix, Inc. (Codagenix), having a place of business in Farmingdale, New York, U.S.A.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before August 18, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Peter Soukas, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Email: ps193c@nih.gov; Telephone: (301) 496-2644; Facsimile: (240) 627-3117.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application Number 63/023,949, filed May 13, 2020 and PCT Patent Application Number PCT/US2021/32305, filed May 13, 2021, entitled "Improved Live-Attenuated Vaccine for Respiratory Syncytial Virus (RSV) Bearing Codon-Pair Deoptimized NS1, NS2, N, P, M and SH Genes and Additional Point Mutations in the P Gene," [HHS Reference No. E-104-2020-0]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to: "Live-attenuated codon-deoptimized human respiratory syncytial virus vaccine."

RSV is the most important viral agent of severe respiratory disease in infants and young children worldwide and also causes substantial morbidity and mortality in older adults. RSV is estimated to cause more than 33 million lower respiratory tract illnesses, three million hospitalizations, and nearly 200,000 childhood deaths worldwide annually, with many deaths occurring in developing countries. However, despite the prevalence of RSV and the dangers associated with infection, no RSV vaccine has been successfully developed to date. Accordingly, there is a public health need for RSV vaccines. This vaccine candidate comprises live RSV that was attenuated by subjecting the protein-coding sequences of the viral NS1, NS2, N, P, M, and SH genes to codon-pair deoptimization, which resulted in many nucleotide substitutions that were silent at the amino acid level but conferred attenuation. In addition, specific amino acid substitutions were identified and introduced into the P protein that improved attenuation and genetic stability. Genetic stability was confirmed in vitro, and attenuation was confirmed in experimental animals.

This live-attenuated RSV vaccine is designed to be administered intranasally by drops or spray to infants and young children. Based on experience with other live-attenuated RSV vaccine candidates, the present candidates are anticipated to be well tolerated in humans and are available for clinical evaluation. The National Institute of Allergy and Infectious Diseases has extensive experience and capability in evaluating live-attenuated RSV vaccine candidates in pediatric clinical studies.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications

submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-16462 Filed 8-2-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA-2021-0016; OMB No. 1660-0086]

Agency Information Collection Activities: Proposed Collection; Comment Request; National Flood Insurance Program—Mortgage Portfolio Protection Program (MPPP); Ask the Advocate Web Form

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a previously approved information collection for which approval has expired. FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning an amendment to a currently-approved collection of information related to the National Flood Insurance Program (NFIP), Mortgage Portfolio Protection Program (MPPP), which is an option that companies participating in the National Flood Insurance Program can use to bring their mortgage loan portfolios into compliance with the flood insurance purchase requirements. This amended notice seeks comments concerning the collection of information related to the Office of the Flood Insurance Advocate (OFIA).

DATES: Comments must be submitted on or before September 2, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

For information related to the NFIP Mortgage Portfolio Protection Program (MPPP), contact Kelly Bronowicz, Industry Management Branch Chief, FEMA, at 202-557-9488, or Kelly.Bronowicz@fema.dhs.gov.

For information related to the Ask the Advocate web form, contact Joe Cecil, Advocate Representative Team Lead, Office of the Flood Insurance Advocate, FEMA, at 202-701-3465, or Joseph.Cecil@fema.dhs.gov.

Requests for additional information or copies of the information collection should be made to the Forms & Information Collections Manager, Information Management Division, 500 C Street SW, Washington, DC 20472, email address FEMA-Information-Collections-Management@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: Pertaining to the MPPP, federal lenders and Federally-regulated or sponsored lending institutions may not make, increase, extend, or renew any loan secured by improved real property located in a special flood hazard area (SFHA) unless the building and any personal property securing the loan is covered by flood insurance for the life of the loan. See Flood Disaster Protection Act of 1973 (FDPA) § 102 (Pub. L. 93-234; 42 U.S.C. 4012a). The FEMA Administrator carries out the NFIP to enable interested persons to purchase insurance against loss resulting from physical damage to or loss of real or personal property arising from flood in the United States. See National Flood Insurance Act of 1968 (NFIA) (Pub. L. 90-448, title XIII; 42 U.S.C. 4001 *et seq.*).

In general, individual mortgagees subject to the requirements of the FDPA obtain and maintain flood insurance for their individual properties. When individual mortgagees do not obtain required flood insurance, the NFIP's Mortgage Portfolio Protection program (MPPP) allows covered lenders to ensure compliance with the requirements of FDPA by selling making available special coverage for the lender's entire mortgage portfolio. See 44 CFR 62.23(l). In order sell MPPP policies, private insurance companies participating in the NFIP's Write Your

Own (WYO) Program must apply for and annually renew their election to voluntarily participate in the MPPP.

This proposed information collection previously published in the **Federal Register** on May 25, 2021, at 86 FR 28122 with a 60-day public comment period. No comments were received. This information collection expires on December 31, 2021. FEMA is requesting a revision of this currently approved collection. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Pertaining to the Ask the Advocate Web Form, Section 24 of the Homeowner Flood Insurance Affordability Act of 2014 (42 U.S.C. 4033), Public Law 113-89, 128 Stat. 1030, requires FEMA to designate a Flood Insurance Advocate that would advocate for the fair treatment of NFIP policyholders and property owners by: (1) Providing education and guidance on all aspects of the NFIP, (2) identifying trends affecting the public, and (3) making recommendations for NFIP program improvements to FEMA leadership. Pursuant to this authority, FEMA established the Office of the Flood Insurance Advocate (OFIA) on December 22, 2014.

Members of the public regularly contact OFIA seeking assistance on the NFIP. OFIA seeks to facilitate the timely and effective management of these inquiries by creating a web form on OFIA's web page at <https://www.fema.gov/flood-insurance/advocate>. The web form will allow users to provide information that includes all the data necessary for OFIA to perform its Congressionally-mandated duties and responsibilities.

Consumers who submit an inquiry to OFIA will be required to fill-out ten (10) informational fields on the Ask the Advocate web form. These fields include: (1) First name, (2) Last name, (3) Email address, (4) Confirm email address, (5) How did you hear of Advocate's office (pull-down list), (6) Contact role (list field), (7) State (pull-down list), (8) ZIP code, (9) Subject (of inquiry) and (10) Questions/Comment (regarding inquiry). An eleventh (11th) field is a security CAPTCHA field intended to distinguish human from machine input as a way of thwarting spam and automated extraction of data from websites.

When a consumer submits this information, the data will be collected and stored on OFIA's Department of Homeland Security/FEMA-approved Customer Relationship Management

cloud-based environment hosted by Salesforce.

Once OFIA receives this information, the inquiry will be assigned a system-generated “Case number”, and then the case is then assigned to an OFIA Advocate Representative (FEMA employee). Using the data collected from the Ask the Advocate web form, the Advocate Representative will research the customer's inquiry and offer education and guidance to help the customer navigate the NFIP process.

Collection of Information

Title: National Flood Insurance Program—Mortgage Portfolio Protection Program (MPPP).

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660-0086.

FEMA Forms: Ask the Advocate Web Form (form number pending OMB approval).

Abstract: Regarding the MPPP, FEMA needs the information to ensure that private insurance companies that join the NFIP's WYO Program meet all state and federal requirements for insurance companies. Requirements include a good business record and satisfactory rating in their field. There is no other way to obtain this information because it is specific to each company that applies to join the NFIP.

Regarding the Ask the Advocate Web Form, the Homeowner Flood Insurance Affordability Act of 2014 requires FEMA to designate a Flood Insurance Advocate that would advocate for the fair treatment of NFIP policyholders and property owners. Pursuant to this authority, FEMA established OFIA on December 22, 2014.

Members of the public regularly contact OFIA seeking assistance on the NFIP. OFIA seeks to facilitate the timely and effective management of these inquiries through a web form on OFIA's web page. The web form will allow users to provide information that includes all the data necessary for OFIA to fulfill its duties and responsibilities.

Affected Public: Individuals, households, businesses, or other for-profit.

Estimated Number of Respondents: 1,041.

Estimated Number of Responses: 1,041.

Estimated Total Annual Burden Hours: 227.

Estimated Total Annual Respondent Cost: \$11,856.

Estimated Respondents' Operation and Maintenance Costs: \$0.00.

Estimated Respondents' Capital and Start-Up Costs: \$0.00.

Estimated Total Annual Cost to the Federal Government: \$71,930.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Millicent L. Brown,

Senior Manager, Records Management Branch, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2021-16507 Filed 8-2-21; 8:45 am]

BILLING CODE 9111-52-P

DEPARTMENT OF HOMELAND SECURITY

[DHS Docket No. ICEB-2021-0008]

RIN 1653-ZA20

Employment Authorization for Haitian F-1 Nonimmigrant Students Experiencing Severe Economic Hardship as a Direct Result of the Current Crisis in Haiti

AGENCY: U.S. Immigration and Customs Enforcement (ICE), DHS.

ACTION: Notice.

SUMMARY: This notice announces that the Secretary of Homeland Security (Secretary) has suspended certain regulatory requirements for F-1 nonimmigrant students whose country of citizenship is Haiti (regardless of country of birth) and who are experiencing severe economic hardship as a direct result of the current crisis in Haiti. The Secretary is taking action to provide relief to Haitian citizens who are lawful F-1 nonimmigrant students so the students may request employment authorization, work an increased number of hours while school is in session, and reduce their course

load while continuing to maintain F-1 nonimmigrant student status. DHS will deem an F-1 nonimmigrant student who receives employment authorization by means of this notice to be engaged in a "full course of study" for the duration of the employment authorization, if the nonimmigrant student satisfies the minimum course load requirement described in this notice.

DATES: This F-1 notice is effective August 3, 2021 through February 3, 2023.

FOR FURTHER INFORMATION CONTACT: Sharon Snyder, Unit Chief, Policy and Response Unit, Student and Exchange Visitor Program, MS 5600, U.S. Immigration and Customs Enforcement, 500 12th Street SW, Washington, DC 20536-5600; email: sevp@ice.dhs.gov, telephone: (703) 603-3400. This is not a toll-free number. Program information can be found at <http://www.ice.gov/sevis/>.

SUPPLEMENTARY INFORMATION:

What action is the Department of Homeland Security (DHS) taking under this notice?

The Secretary of Homeland Security is exercising authority under 8 CFR 214.2(f)(9) to temporarily suspend the applicability of certain requirements governing on-campus and off-campus employment for F-1 nonimmigrant students whose country of citizenship is Haiti (regardless of country of birth) who are present in the United States in lawful F-1 nonimmigrant student status as of August 3, 2021, and who are experiencing severe economic hardship as a direct result of the current crisis in Haiti. DHS initially suspended certain regulatory requirements for F-1 nonimmigrant students experiencing severe economic hardship as a direct result of the January 12, 2010 earthquake in Haiti. *See* 75 FR 56120 (Sep. 15, 2010). The original notice was effective from September 15, 2010, until July 22, 2011. A subsequent notice provided for an 18-month extension from July 22, 2011, through January 22, 2013. *See* 76 FR 28997 (May 19, 2011). A third notice provided another 18-month extension from January 22, 2013, through July 22, 2014. *See* 77 FR 59942 (Oct. 1, 2012). A fourth notice provided for another 18-month extension from July 22, 2014, through January 22, 2016. *See* 79 FR 11805 (Mar. 3, 2014). A fifth notice provided for another 18-month extension from January 22, 2016, through July 22, 2017. *See* 80 FR 51579 (Aug. 25, 2015). Effective with this publication, suspension of the employment limitations is available through February 3, 2023, for those who

are in lawful F-1 nonimmigrant status as of August 3, 2021. DHS will deem an F-1 nonimmigrant student granted employment authorization through this notice to be engaged in a "full course of study," for the duration of the employment authorization if the student satisfies the minimum course load set forth in this notice.¹ *See* 8 CFR 214.2(f)(6)(i)(F).

Who is covered by this notice?

This notice applies exclusively to F-1 nonimmigrant students who meet all of the following conditions:

- (1) Are citizens of Haiti, regardless of country of birth;
- (2) Were lawfully present in the United States in an F-1 nonimmigrant status on August 3, 2021, under section 101(a)(15)(F)(i) of the Immigration and Nationality Act (INA), 8 U.S.C. 1101(a)(15)(F)(i);
- (3) Are enrolled in an institution that is Student and Exchange Visitor Program (SEVP)-certified for enrollment of F-1 nonimmigrant students;
- (4) Are maintaining F-1 status; and
- (5) Are experiencing severe economic hardship as a direct result of the current crisis in Haiti.

This notice applies to F-1 nonimmigrant students in an approved private school in grades kindergarten through grade 12, public school in grades 9 through 12, and undergraduate and graduate education. An F-1 nonimmigrant student covered by this notice who transfers to another SEVP-certified academic institution remains eligible for the relief provided by means of this notice. Nothing in this notice affects the applicability of federal and state labor laws limiting the employment of minors.

Why is DHS taking this action?

As a result of the current crisis in Haiti, the Secretary designated Haiti for Temporary Protected Status (TPS) for 18 months, effective August 3, 2021 through February 3, 2023, based on extraordinary and temporary conditions

¹ Because the suspension of requirements under this notice applies throughout an academic term during which the suspension is in effect, DHS considers an F-1 nonimmigrant student who engaged in a reduced course load or employment (or both) after this notice is effective to be engaging in a "full course of study," *see* 8 CFR 214.2(f)(6), and eligible for employment authorization, through the end of any academic term for which such student is matriculated as of February 3, 2023, provided the student satisfies the minimum course load requirements in this notice. DHS also considers students who engage in online coursework pursuant to ICE coronavirus disease 2019 (COVID-19) guidance for nonimmigrant students to be in compliance with regulations while such guidance remains in effect. *See* ICE Guidance on COVID-19, available at <https://www.ice.gov/coronavirus> [last visited May 2021].